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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,330

02/13/2007

Colin Dickens

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EXAMINER

OSINSKI, BRADLEY JAMES

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,330	<b>Applicant(s)</b> DICKENS ET AL.	
	<b>Examiner</b> BRADLEY J. OSINSKI	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-14-2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear what the "Defined size" is attempting to claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17-21 recites the limitation "the defined size" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (2004/0112378) in view of Mishelevich et al (5,363,842).

a. Regarding claims 1 and 27, Djupesland discloses a nasal device in paragraph 211 to release an aerosol to the nasal turbinates past the nasal valve. In paragraph 210 a substantially gas-tight seal is disclosed. Paragraph 204 discloses an aerosol containing medicament. However, while Djupesland substantially discloses the method as claimed, it does not disclose preventing further gas flow for a time period to allow the particles to settle on the tissue.

Mishelvehich et al discloses an aerosol inhaler in which the patient holds his or her breath for 10 seconds to allow smaller particles to settle. (Col.2 lines 20-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a patient utilizing the device of Djupesland hold his/her breathe for 10 seconds to allow smaller particles to settle.

b. Regarding claim 2, Djupesland discloses aerodynamic diameters of about 8 microns being deposited in the nasal passageway (Paragraph 2)

c. Regarding claims 3, 22-26 and 30, While Djupesland substantially discloses the method as claimed such as delivering medication to the turbinate region, it does not disclose delivery volumes. Mishelevich et al discloses low inhalation rates below one liter per second to minimize loss of medicine through impact with various tissues, but does not disclose a delivery time. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the volume of the turbinate region and nasal

vestibule and deliver an appropriate amount, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

d. Regarding claim 4, See paragraphs 210 and 211 of Djupesland which disclose sealing the nostril.

e. Regarding claims 5-9, see claim 1 above, Mishelevich et al teaches holding ones breathe up to 10 seconds. (Col.2 lines 28-29)

f. Regarding claims 10-15, See claims 1 and 2 above, Mishelevich teaches holding ones breathe up to 10 seconds and Djupesland discloses an 8 micron diameter.

g. Regarding claims 16-21, Djupesland discloses the claimed invention except for the mass percent of active material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the weight percentages of the various particles in the gas, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

4. Claims 28 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (2004/0112378) in view of Ruskewicz (5,971,951) and Mishelevich et al (5,363,842).

h. Regarding claims 28 and 29, while Djupesland substantially discloses the apparatus as claimed (see claims 1 and 2 above), it does not disclose means for indicating when a predetermined time period has elapsed after actuation of the delivery means or means for determining when a volume of gas has passed through the nozzle. However, Ruskewicz discloses a microprocessor for aerosol devices that discloses both audible and visual displays. The audible display activates if the patient has not delivered the full amount of medication (Col. 36 lines 50-52) and a visual display after a predetermined dose has been delivered (Col. 36 lines 47-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include audio and visual alerts as taught by Ruckewicz to the device of Djupesland to warn a patient when to take his or her medications and when the medication has been fully administered.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767